

FIRST REGULAR SESSION

# SENATE BILL NO. 538

101ST GENERAL ASSEMBLY

INTRODUCED BY SENATOR BURLISON.

2644S.01H

ADRIANE D. CROUSE, Secretary

## AN ACT

To repeal section 338.165, RSMo, and to enact in lieu thereof one new section relating to pharmacy services in hospitals.

*Be it enacted by the General Assembly of the State of Missouri, as follows:*

Section A. Section 338.165, RSMo, is repealed and one new  
2 section enacted in lieu thereof, to be known as section 338.165,  
3 to read as follows:

338.165. 1. As used in this section, the following  
2 terms mean:

3 (1) "Board", the Missouri board of pharmacy;

4 (2) "Hospital", a hospital as defined in section  
5 197.020;

6 (3) "Hospital clinic or facility", a clinic or  
7 facility under the common control, management, or ownership  
8 of the same hospital or hospital system;

9 (4) "Medical staff committee", the committee or other  
10 body of a hospital or hospital system responsible for  
11 formulating policies regarding pharmacy services and  
12 medication management;

13 (5) "Medication order", an order for a legend drug or  
14 device that is:

15 (a) Authorized or issued by an authorized prescriber  
16 acting within the scope of his or her professional practice  
17 or pursuant to a protocol or standing order approved by the  
18 medical staff committee; and

**EXPLANATION-Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.**

(b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

(6) "Patient", an individual receiving medical diagnosis, treatment or care at a hospital or a hospital clinic or facility.

2. The department of health and senior services shall have sole authority and responsibility for the inspection and licensure of hospitals as provided by chapter 197 including, but not limited to all parts, services, functions, support functions and activities which contribute directly or indirectly to patient care of any kind whatsoever. However, the board may inspect a class B pharmacy or any portion thereof that is not under the inspection authority vested in the department of health and senior services by chapter 197 to determine compliance with this chapter or the rules of the board. This section shall not be construed to bar the board from conducting an investigation pursuant to a public or governmental complaint to determine compliance by an individual licensee or registrant of the board with any applicable provisions of this chapter or the rules of the board.

3. The department of health and senior services shall have **the sole** authority to promulgate rules **governing inpatient pharmacy services in hospitals, but may promulgate rules** in conjunction with the board governing medication distribution and the provision of medication therapy services, **as described in section 338.010**, by a pharmacist at or within a hospital. [Rules may include, but are not limited to, medication management, preparation, compounding, administration, storage, distribution, packaging and labeling. Until such rules are jointly promulgated,

51 hospitals shall comply with all applicable state law and  
52 department of health and senior services rules governing  
53 pharmacy services and medication management in hospitals.]

54 **The board shall have the sole authority to promulgate rules**  
55 **governing inspection and licensure of class B pharmacies.**

56 The rulemaking authority granted herein to the department of  
57 health and senior services shall not include the dispensing  
58 of medication by prescription.

59 4. All pharmacists providing medication therapy  
60 services shall obtain a certificate of medication  
61 therapeutic plan authority as provided by rule of the  
62 board. Medication therapy services may be provided by a  
63 pharmacist for patients of a hospital pursuant to a  
64 protocol with a physician as required by section 338.010 or  
65 pursuant to a protocol approved by the medical staff  
66 committee. However, the medical staff protocol shall  
67 include a process whereby an exemption to the protocol for a  
68 patient may be granted for clinical efficacy should the  
69 patient's physician make such request. The medical staff  
70 protocol shall also include an appeals process to request a  
71 change in a specific protocol based on medical evidence  
72 presented by a physician on staff.

73 5. Medication may be dispensed by a class B hospital  
74 pharmacy pursuant to a prescription or a medication order.

75 6. A drug distributor license shall not be required to  
76 transfer medication from a class B hospital pharmacy to a  
77 hospital clinic or facility for patient care or treatment.

78 7. Medication dispensed by a class A pharmacy located  
79 in a hospital to a hospital patient for use or  
80 administration outside of the hospital under a medical staff-  
81 approved protocol for medication therapy shall be dispensed

only by a prescription order for medication therapy from an individual physician for a specific patient.

8. Medication dispensed by a hospital to a hospital patient for use or administration outside of the hospital shall be labeled as provided by rules jointly promulgated by the department of health and senior services and the board including medication distributed for administration by or under the supervision of a health care practitioner at a hospital clinic or facility.

9. This section shall not be construed to preempt any law or rule governing controlled substances.

10. Any rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall only become effective if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2014, shall be invalid and void.

11. The board shall appoint an advisory committee to review and make recommendations to the board on the merit of all rules and regulations to be jointly promulgated by the board and the department of health and senior services pursuant to the joint rulemaking authority granted by this section. The advisory committee shall consist of:

(1) Two representatives designated by the Missouri Hospital Association, one of whom shall be a pharmacist;

(2) One pharmacist designated by the Missouri Society of Health System Pharmacists;

114           (3) One pharmacist designated by the Missouri Pharmacy  
115 Association;

116           (4) One pharmacist designated by the department of  
117 health and senior services from a hospital with a licensed  
118 bed count that does not exceed fifty beds or from a critical  
119 access hospital as defined by the department of social  
120 services for purposes of MO HealthNet reimbursement;

121           (5) One pharmacist designated by the department of  
122 health and senior services from a hospital with a licensed  
123 bed count that exceeds two hundred beds; and

124           (6) One pharmacist designated by the board with  
125 experience in the provision of hospital pharmacy services.

126           12. Nothing in this section shall be construed to  
127 limit the authority of a licensed health care provider to  
128 prescribe, administer, or dispense medications and  
129 treatments within the scope of their professional practice.

✓